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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/648,123 08/25/00 STANTON

V 030586.0009.

EXAMINER

HM12/0410

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12390 EL CAMINO REAL
SAN DIEGO CA 92130

WILDER, C

ART UNIT

PAPER NUMBER

1655

2

DATE MAILED:

04/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/648,123

Applicant(s)

STANTON, V.

Examiner

CB Wilder

Group Art Unit

1655



☒ Responsive to communication(s) filed on Aug 25, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-16 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-16 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claim 1-14, drawn to a isolated nucleic acid probe, classified in class 536, subclass 24.3.
 - II. Claims 15 and 16, drawn to a method of determining the presence of a variance in a gene, classified in class 435, subclass 6.
2. The inventions are distinct, each from the other because of the following reasons: ~~Inventions~~
I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product consisting of an isolated nucleic acid probe of Invention I can be used in a materially different process such as in chromosomal in situ hybridization or in DNA sequencing analysis or in aptamer studies.
3. Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for the Group, restriction for examination purposes as indicated is proper.

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4. Groups I and II each contain claims with regard to specific variance of a gene. Election of one single variance and the corresponding gene is required, along with one of Groups I and II. The broad claims will be examined along with the single variance and corresponding gene which is elected.

5. Each of the variance is unrelated to each other variance of a gene. Invention are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the different inventions are unrelated because each variance differs in structure and effect from each other variance. Specifically, the chemical structure of any one variance is necessarily different from that of any other variance because where, for example, as listed in Table 3, the variance comprising a nucleic acid with an A to G substitution at position 655 of the glutamate dehydrogenase gene is chemically and structurally different the nucleic acid with a G to A substitution at position 898 of the glutamate dehydrogenase gene. Likewise, the different variance of the glutamate dehydrogenase gene are chemically, structurally and functionally different from the variance comprising nucleic acid sequences as recited in Table 3 for the Cytochrome P-450 gene, the Human acyl coenzyme A:cholesterol acyltransferase gene, Homo sapiens P-type ATPases FIC1 gene, Human neutral amino acid transporter B gene, Human E16 gene, H. Sapiens canalicular multidrug resistance protein, Human organic anion transporting polypeptide (OATP), Carboxylesterase I gene, and the H. Sapiens REC1L gene. These variant changes cause different effects in the different genes, as well as clearly resulting in different structures.

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6. Two requirements are cited in 37 C.F.R. 1.142 to permit restriction. "If two or more independent and distinct inventions are claimed in a single application, the examiner in his/her action shall require the Applicant in his/her response to that action elect that invention to which his/her claim shall be restricted, this official action being called a requirement for restriction (also known as a requirement for division). If the distinctness and independence of the invention be clear, such requirement will be made before any action on the merits; however, it may be made at any time before final action in the case, and the discretion of the examiner."

These two requirements are that the invention be independent and distinct. MPEP 802.02 notes regarding the independent requirement that "The term "independent" (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect". Here, the variance is unconnected to each other variance in design, since they differ in structure, The variance are different in operation, since they act at different sites in the same gene and in other genes to cause different effects, as noted above. With regard to the distinct requirement, the MPEP 802.02 notes "The term "distinct" means that two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made, et c., but are capable separate manufacture, use or sale as claimed, a **AND ARE PATENTABLE** (novel and unobvious) **OVER EACH OTHER** (though they may each be unpatentable because of the prior art)." Thus, the specific requirement is that the inventions are capable of separate use, which is clearly evident in this

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application regarding these variances both by the separate claiming and because each variance can be separately screened. Further, each variance is separately patentable over each other variance.

7. Because these invention are distinct for the reasons given above and the search required for any one group is not required for any other groups, restriction for examination purposes as indicated is proper. Specifically, the search for each variance would require a search of the literature, which would differ, since some variance would be searched by identifying mutations, for example, in the introns, 5' region, or 3' region while other mutations would be search in any series of different genes such as those mentioned above.

8. A telephone call was made to Mr. Wesley Ames on March 8, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made. Mr. Ames requested a written restriction be made.

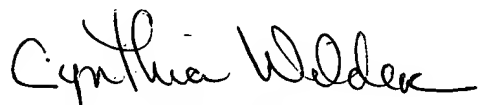
9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

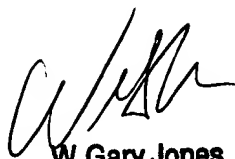
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed the Group's receptionist whose telephone number is (703) 308-0196.



Cynthia B. Wilder, Ph.D.

April 9, 2001



W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

4/9/01